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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/616,778	07/10/2003	Mitchell S. Wortzman	01-40076-USD2	1999

7590 08/09/2004

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EXAMINER

HOWARD, SHARON LEE

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 08/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/616,778

Applicant(s)

WORTZMAN ET AL.

Examiner

Sharon L. Howard

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 54-76 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 54-76 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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The examiner acknowledges receipt of the preliminary amendment filed on 7/10/03.

Claims 1-53 and 77-106 have been cancelled.

Claim 78 has been amended.

Claims 54-76 are pending.

### **DETAILED ACTION**

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 54-76 rejected under 35 U.S.C. 103(a) as being unpatentable over Gordon et al. (U.S. Patent No. 5,932,612).

Gordon teaches a method of using a skin lightening composition and for treating hyperpigmentation (see abstract). Gordon teaches about 0.05 to about 10% of ascorbic acid derivatives (see claim 22), such as magnesium ascorbyl

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phosphate and ascorbityl palmitate which can be used in the composition (see col.1, lines 64-67), as well as 1.5 to 4.0% of hydroquinone and other skin lightening agents (see col.2, lines 66-67, bridging col.3, lines 1 and 2). See Table 1 at col.2 for the teaching of 1.50 % w/w of ascorbyl palmitate, 0.15 % w/w of sodium bisulfite and other ingredients known in the art, prepared in a liquid, a gel or a cream formulation. Gordon teaches that according to the severity of the hyperpigmentation and the sensitivity of the affected skin area, the amount of the composition that is to be applied to the skin will vary, that is to say, usually from about 0.25 g to about 0.50 g of the cream which is described at col.2, lines 51-65 and see col.3, lines 3-10.

With respect to the silent teaching of the composition having a specific pH of about 5.5 to about 8.0, the pH is an inherent characteristic and is encompassed therein. The Gordon reference discloses the same composition, having properties to be desired such as reduced skin irritation and treating hyperpigmentation, while providing skin lightening which is known to be at least as effective as the conventional over-the-counter preparations (see abstract).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the Gordon reference, because Gordon teaches applicant's method of combining hydroquinone and derivatives of ascorbic acid, known for the purpose of lightening the skin and reducing skin irritation in a composition containing hydroquinone.

Thus, the expected result would be to obtain a composition containing ascorbic acid derivative(s), hydroquinone, including other conventional

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ingredients, which is known to be effective for reducing side effects such as skin irritation and hyperpigmentation.

### ***Double Patenting***

Claims 54-76 of this application conflict with claims 77-106 of Application No. 10/616,813. 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.

Claims 54-76 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 77-106 of copending Application No. 10/616,813. Although the conflicting claims are not identical, they are not patentably distinct from each other because Application No. 10/616,778 is genus and Application No. 10/616,813 is species. Application No. 10/616,778 is claiming a method of stabilizing a hydroquinone composition having a pH of about 5.5 to about 8.0 comprising adding a cationic salt of acidic ascorbyl esters, wherein said composition further comprises a water-soluble antioxidant, which is generic to a method of stabilizing a hydroquinone composition having a pH of about 5.5 to about 8.0 comprising adding a cationic salt of acidic ascorbyl esters; and adding an protected retinoid.

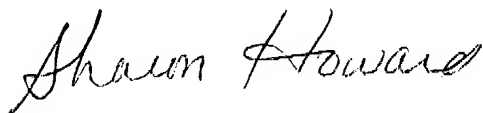
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This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

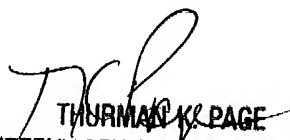
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon L. Howard whose telephone number is (571) 272-0596. The examiner can normally be reached on 9:00am - 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Sharon Howard  
July 7, 2004



THURMAN K. PAGE  
SUPERVISORY PATENT EXAMINER  
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